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EXAMINER	
BARNHART, LORA ELIZABETH	
ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 07/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/009,527	SCHAEFER ET AL.	
	Examiner	Art Unit	
	Lora E. Barnhart	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36-39 and 41-67* is/are pending in the application.

4a) Of the above claim(s) *45-66* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36-39,41-44 and 67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The reply received 4/24/06 amending claims 36 and 67 and canceling claim 40 is acknowledged. Claims 36-39 and 41-67 are currently pending, of which 36-39, 41-44, and 67 are being examined on the merits.

Prior art references can be found in a prior Office action, unless otherwise noted.

Specification

The objection to the specification is withdrawn in light of the submission of the substitute specification.

Claim Objections

The objections to the claims are withdrawn in light of the claim amendments.

Claim Rejections - 35 USC § 112

The rejections of record under 35 U.S.C. § 112, second paragraph, are withdrawn in light of the claim amendments.

Claim Rejections - 35 USC § 102

Claims 36 and 37 remain rejected under 35 U.S.C. 102(b) as being anticipated by Itay (U.S. Patent 5,053,050) taken in light of Thomas (*Taber's Cyclopedic Medical Dictionary*, 18th ed.) and Boden (*Clinical Orthopedics* 376: S84-S94). The claims are drawn to a composition comprising at least one biocompatible carrier material, cartilaginous tissue, and osseous tissue, such that one surface of said composition consists of cartilaginous tissue and the opposite surface consists of osseous tissue. In some dependent claims, the composition's size and shape match the portion of the joint to be replaced.

As discussed previously, Itay teaches a composition produced *in vitro*, comprising a biocompatible carrier material (e.g. fibrinogen-based adhesive matrix) and chondrocytes, which are implanted into defective bones (Examples 1-3 and The Process). Additionally, the composition of Itay can be produced in any shape, including cylinders (column 4, line 68) and the precise shape of the damaged area (column 5, lines 3-4), and in any size (Example 3). Thomas is cited as evidence that synovial joints comprise two bones, each with a layer of articular cartilage coating the epiphyseal end (p. 1035) and that bone tissue comprises endothelial cells, i.e. blood vessels (page 249). Boden is cited as evidence that bone tissue contains growth factors (page 3, *e.g.*).

Applicant alleges that the term "joint construct" "connotes a definite structural articulation [that] cannot reasonably be associated with [Itay]" (Reply, page 11, paragraph 4). Applicant alleges that Itay does not teach "in vitro opposite side by side placement on biocompatible materials" (Reply, page 11, paragraph 6). These arguments have been fully considered, but they are not persuasive.

The term "joint construct" is not defined in the specification in terms of "a definite structural articulation", but rather in terms of its components (page 3, lines 2-7). The phrase "definite structural articulation" does not appear anywhere within the original specification. Indeed, the **claims** do not recite or reasonably imply a "definite structural articulation" either explicitly or in light of the specification as filed. The examiner queries applicant's characterization of Itay as "alleged prior art," since the specification clearly cites Itay as analogous art (page 1, lines 22-25).

The examiner agrees that the term "*in vitro*" is defined particularly in the specification as "a process [that] takes place outside the human or animal body" (page 2, lines 35-36) but points out that applicant is not claiming an *in vitro* construct, but rather a construct "produced at least partly *in vitro*." The scope clearly differs between the two phrases. In any case, as discussed previously, claim 36 is a product-by-process claim (see M.P.E.P. §2113), and, as such, the process limitations "produced at least partly *in vitro*," "cultured chondrocytes," and "cultured osteocytes" are considered only to the extent that they affect the **structure** of the claimed composition.

In short, it is not clear whether a composition made by culturing chondrocytes on one end of a piece of carrier material and culturing osteocytes on the other end is patentably distinct from the composition of Itay (which comprise bone tissue on one end and cartilage on the other). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983). Similarly, in *Ex parte Gray*, 10 USPQ2d 1922 (Bd. Pat. App. & Inter. 1989), the Board stated that the dispositive issue is whether the claimed composition exhibits any unexpected properties compared with the composition disclosed by the prior art and that the applicant should have made some comparison between the claimed composition and the composition of the prior art to establish unexpected properties, since the compositions appeared to be identical or only slightly different.

Applicant alleges that Itay "starts off with a composition of either chondrogenic cells or osteogenic cells in vitro but not both" (Reply, page 12, paragraph 1). However, this rejection is not made over the starting material of Itay, but rather over the finished product (the composition comprising bone, cartilage, and a carrier material that results from the implantation of the starting material in bone). In fact, the **claims** do not recite any structural properties that would distinguish the claimed composition over the composition of Itay (*e.g.*, a composition made by implanting bone tissue into a bone defect site and allowing cartilage to cover the implanted tissue naturally). The claims are, in fact, sufficiently broad as to encompass natural bone tissue. Furthermore, the composition comprises "cartilaginous substance" and "osseous substance," which are broadly defined in the as-filed specification at page 5, lines 11-17 and 21-29, respectively, and include numerous components that are not cartilage, bone, or carrier material. Therefore, differences between the instantly claimed composition and the composition of Itay are not immediately evident.

Finally, applicant's arguments about "in vitro opposite side by side placement on biocompatible materials" are confusing, since this phrase is not defined or even recited in the specification. The claim requires only that the composition have two "sides" but does not require that they be on opposing faces of the composition.

Claims 36-39, 41-44, and 67 remain rejected under 35 U.S.C. 102(b) as being anticipated by Jakob et al. (WO 99/21497; and German-to-English translation). The claims are drawn to a composition comprising at least one biocompatible carrier

material, cartilaginous tissue, and osseous tissue, such that one surface of said composition consists of cartilaginous tissue and the opposite surface consists of osseous tissue. In some dependent claims, the composition's size and shape match the portion of the joint to be replaced. In some dependent claims, the composition has a circular cross-section. The page and paragraph numbers in this rejection refer to the English translation.

Jakob et al. teach a composition comprising bone adhered to cartilage that has been removed from a donor site (page 2, paragraph 3; Figures 1, 5-7, 9, and 10). The composition of Jakob et al. is a column of tissue comprising cartilage adhered firmly to bone (Figure 1; page 7, paragraph 1) and comprises a biocompatible carrier material in the respect that it is obtained from the patient's own body. Jakob et al. also teach a composition comprising cartilage cells cultured *in vitro* on bone-replacement material (page 5, paragraph 3; page 16, paragraph 3; Figures 11 and 12). The composition of Jakob et al. may have a circular cross-section (page 11, paragraph 4; page 12, paragraph 4; and Figures 13-16) or may have any shape (page 15, paragraph 3). The composition of Jakob et al. is cylindrical, thus fulfilling the requirements of claim 38, and comprises bone, which naturally comprises growth factors, thus fulfilling the requirements of claim 37.

The invention of Jakob et al. fulfills the requirements of claim 42 in that numerous tissue columns may be placed into a single defect such that their joint sides (*i.e.*, cartilage) are contacting one another (see, for example, Figure 5 and page 11, paragraph 3). The limitation that the anchor sides are in two different bone shafts has

not been considered, since this is an optional limitation in the claims. The invention of Jakob et al. fulfills the requirements of claims 39, 43, and 44 in the respect that it comprises placing the tissue columns into live bone, which comprises ligaments and a joint capsule. The invention of Jakob et al. inherently comprises the limitations of claims 39, 43, and 44.

Claims 36-39, 41-44, and 67 are product-by-process claims. M.P.E.P. § 2113 reads, "Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps." As such, the limitations "produced *in vitro*," "cultured chondrocytes and/or chondroblasts," and "cultured osteoblasts and/or osteocytes" have been evaluated only to the extent that they affect the structure of the composition.

"Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive

structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979)

The use of 35 U.S.C. §§ 102 and 103 rejections for product-by-process claims has been approved by the courts. "[T]he lack of physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, it is the patentability of the product claimed and not of the recited process steps which must be established. We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

Applicant alleges, "no where [*sic*] did Jakob et al. contemplate, suggest, envisage, teach or render obvious, the making of [an] artificial joint construct comprising both cultured cartilaginous cells and cultured osseous cells immobilized or anchored in/on opposite sides of at least one biologically compatible material" (Reply, page 12, paragraph 5, through page 13, paragraph 1). Applicant further alleges that natural bone tissue does not "have the same structure as tissue engineered bone-substitutes of the present invention" (Reply, page 13, paragraph 2; with detail on pages 13-17). These arguments have been fully considered, but they are not persuasive.

First, applicant's arguments about "cells immobilized or anchored in/on opposite sides of at least one biologically compatible material" are confusing, since this phrase is not recited in the claims. The claims require that the composition have two "sides" but do not require that they be on opposing faces of the composition.

In any case, Jakob et al. do teach compositions as claimed (*i.e.*, compositions comprising a biocompatible carrier material, cartilaginous tissue, and osseous tissue). For example, at page 2, paragraph 3, the English translation reads:

> The autotransplants, in particular, are mostly columns having an outer cartilage face side and an inner bone face side.

Page 2, paragraph 4, through page 3, paragraph 1, reads:

> Tissue columns are then removed from a less strained joint site (e.g. the condyle region of the femur)...the tissue columns that are removed are then inserted into the defect holes.

According to Jakob et al., the "tissue columns" (reference numeral 2 in Figure 1) comprise a cartilage layer (reference numeral 2') and an inner bone part (reference 2") under the cartilage layer (page 7, paragraph 1). Furthermore, page 5, paragraph 3, reads:

> In any case, the implanted tissue columns are advantageously autotransplants removed from a less strained site, but may also be of bone-replacement material, on which in vitro cartilage tissue has previously been cultivated.

Clearly, Jakob et al. teach constructs that comprise all three components required by the claims (a carrier material; cartilage tissue; and bone tissue). The limitations "produced *in vitro*" and "cultured [cells]" in the instant claims do not distinguish over Jakob et al., because these are product-by-process limitations.

In short, it is not clear whether a composition made by culturing chondrocytes on one end of a piece of carrier material and culturing osteocytes on the other end is patentably distinct from the tissue columns of Jakob et al. (which comprise bone tissue on one end and cartilage on the other). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983). Similarly, in *Ex parte Gray*, 10 USPQ2d 1922 (Bd. Pat. App. & Inter. 1989), the Board stated that the dispositive issue is whether the claimed composition exhibits any unexpected properties compared with the composition disclosed by the prior art and that the applicant should have made some comparison between the claimed composition and the composition of the prior art to establish unexpected properties, since the compositions appeared to be identical or only slightly different.

Applicant urges, "natural bone tissue [does not] have the same structure as tissue engineered bone-substitutes of the present invention. In vivo grown bone tissue is vascularized and contains bone trabeculae and bone marrow with hemopoetic [*sic*] and mesenchymal stem cells, progenitor cells, osteoblasts (bone forming cells), osteoclasts (bone resorbing cells)[,] growth factors, extracellular matrix proteins[,] etc." (Reply, page 13, paragraph 2). Applicant further alleges that "tissue engineered bone substitutes present an entirely different morphology [than natural bone]" (Reply, page 14, paragraph 3). These comments and applicant's extensive discussion of the

properties of engineered and natural bone are noted, and the examiner does not dispute that engineered bone is not completely identical to natural bone. However, the **claims** do not recite any structural properties that would distinguish the claimed composition from natural bone. They are, in fact, sufficiently broad as to encompass natural bone tissue. Furthermore, since the composition comprises "cartilaginous substance" and "osseous substance," which are broadly defined in the as-filed specification at page 5, lines 11-17 and 21-29, respectively, and include numerous components that are not cartilage, bone, or carrier material, applicant is incorrect in arguing that the instantly claimed composition does not comprise progenitor cells (see specification, page 5, lines 27-28, for example).

Claims 36-39 and 41 also remain rejected under 35 U.S.C. 102(b) as being anticipated by any of Mears (U.S. Patent 4,553,272), Vacanti et al. (U.S. Patent 5,736,372), and Caplan et al. (U.S. Patent 4,609,551).

Mears teaches a composition comprising cartilage cells on a biocompatible carrier that is implanted into living bone and colonized by osseous tissue, which inherently comprises growth factors (Figure 2 and Example 1).

Vacanti et al. teaches a composition comprising cartilage cells on a biocompatible carrier that is implanted into living bone and colonized by osseous tissue, which inherently comprises growth factors (Examples 1-5, especially Example 5).

Caplan et al. teaches a composition comprising fibroblasts and a growth factor in a fibrin clot that is implanted into living bone and gives rise to both bone and cartilage (Example 4).

The cited claims are product-by-process claims; see M.P.E.P. § 2113 and discussion above. Because the process steps do not materially alter the structure of the claimed composition, Mears, Vacanti et al., and Caplan et al. anticipate the cited claims.

Applicants rely on arguments traversing the above rejections over Itay and Jakob et al. to traverse these rejections. Therefore, the response set forth above to arguments also applies to these rejections.

Claim Rejections - 35 USC § 103

Claims 36-38, 41, 42, 44, and 67 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Itay, Thomas and Boden as applied to claims 36, 37, 40 and 41 above, and further in view of Johnson et al. (U.S. Patent 4,156,296). The claims are drawn to a composition as described above in which at least one cylindrical peg connects the composition to the bone shaft, and to a joint replacement which comprises two joint compositions that contact each other on their joint (cartilaginous) sides. Some dependent claims describe the shape of the composition. Itay does not teach a composition with a peg or a two-composition joint replacement.

As discussed in previous Office actions, Itay teaches a composition produced *in vitro*, comprising a biocompatible carrier material (e.g. fibrinogen-based adhesive matrix) and chondrocytes, which are implanted into defective bones. Additionally, the composition of Itay can be produced in any shape, including cylinders and the precise

shape of the damaged area, and in any size. Thomas is cited as evidence that synovial joints comprise two bones, each with a layer of articular cartilage coating the epiphyseal end and that bone tissue comprises endothelial cells, i.e. blood vessels. Boden is cited as evidence that bone tissue contains growth factors.

As discussed in previous Office actions, Johnson et al. teaches a composition that is anchored into the bone shaft with a cylindrical peg (stems **16** and **19** in Figures 1-4). Johnson et al. also teaches a joint prosthesis comprising two components that engage with each other (Figures 1-4).

The selection of cross-sectional shape clearly would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan recognizing that Itay clearly states that the composition can have a variety of shapes (for example, cuboidal or cylindrical; column 4, lines 67-68), depending on the defect to be filled. A holding of obviousness over the cited claims is therefore clearly required.

The skilled artisan would have had a reasonable expectation of success in adding the cylindrical peg of Johnson et al. to the composition of Itay because the composition of Itay can have any shape or size (column 4, lines 50-52 and 67-68, and column 5, lines 3-6). The skilled artisan would have been motivated to use the peg of Johnson et al. in the composition of Itay for the expected benefit that a peg articulated into the bone shaft would produce a more secure fit than would two flat ends touching.

It would therefore have been obvious to a person of ordinary skill in the art to make the composition of Itay with the peg of Johnson et al. because the composition of Itay can be of any shape and size.

The skilled artisan would also have had a reasonable expectation of success in providing a joint replacement comprising two compositions of Itay because the composition of Itay can be constructed in any shape and size (column 5, lines 3-6). The skilled artisan would have been motivated to provide two of the compositions of Itay as in the joint replacement of Johnson et al. because Johnson et al. discloses that two-member joint replacements (i.e., those consisting of two portions, each of which covers one epiphyseal end in the joint, but which are not necessarily connected into one apparatus) present a problem in that the positioning of the two elements relative to each other so that they function properly is difficult (column 1, lines 32-34).

It would therefore have been obvious to a person of ordinary skill in the art to provide a joint replacement using two of the compositions of Itay because Johnson et al. discloses that single-element joint replacements are more likely to function well than two-element joint replacements. Additionally, diseases such as rheumatoid arthritis often require the replacement of an entire joint, not just the end of one bone.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Applicants rely on arguments traversing the above rejections over Itay and Jakob et al. to traverse this rejection. Therefore, the response set forth above to arguments also applies to this rejection.

Claims 39 and 43 are/remain rejected under 35 U.S.C. 103(a) as being unpatentable over Itay, Thomas, Boden and Johnson et al. as applied to claims 36-38,

41, 42, 44, and 67, above, and further in view of U.S. '660 (Wevers et al.) and Dunn et al. The claims are drawn to biological joint compositions and replacements as described above, with the further limitation that the parts are connected together with ligamentous material. In some dependent claims, the joint replacement has a joint capsule. A joint capsule replacement can be constructed from the same materials as a ligament replacement (p.4 of specification). Itay and Johnson et al. do not teach compositions or replacements with ligaments or joint capsules.

As discussed in a previous Office action, Wevers et al. teaches a prosthetic ligament device comprising an elastic synthetic woven material, the device being securable to bones by use of bone screws (claim 1 and Figures). Dunn et al. teach a ligament analog prepared by seeding collagen scaffolds with fibroblasts that approximates the structure and strength of native ligament tissue. The artificial ligament of Dunn et al. remains viable after implantation into a joint.

A person of ordinary skill in the art would have had a reasonable expectation of success in connecting the parts of the joint replacements of Itay and Johnson et al. with the artificial ligaments of Wevers et al. and Dunn et al. because the artificial ligaments are disclosed as having properties similar to native ligament tissue. The skilled artisan would have been motivated to connect the apparatus parts of Itay and Johnson et al. with the ligament compositions of Wevers et al. and Dunn et al. for the expected benefit of strengthening the replaced joint. The artificial ligament of Wevers et al. in particular is disclosed as having elastic properties closely approximating natural ligament tissue

(Figures 2 and 3), so joining the joint replacement elements with the ligament of Wevers et al. would more closely simulate a natural joint (see Abstract).

It would therefore have been obvious to a person of ordinary skill in the art to connect the compositions of Itay and Johnson et al. with ligament compositions in order to stabilize the replacement joint and to simulate more closely the natural properties of the joint.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Applicants rely on arguments traversing the above rejections over Itay and Jakob et al. to traverse this rejection. Therefore, the response set forth above to arguments also applies to this rejection.

No claims are allowed. No claims are free of the art.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Friday, 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lora E Barnhart

LEB

IRENE MARX
PRIMARY EXAMINER